K093556
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510(k) Summary of Safety and Effectiveness

Applicant:	ConMed Corporation
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Contact Person:	Sarah Rizk Regulatory Affairs Specialist
Telephone Number:	(315) 624-3219
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Date Prepared:	November 13, 2009
Proprietary Name:	VCARE Dx uterine manipulator/injector cannula
Common/Classification Name:	Cannula, Manipulator/Injector, Uterine
Product Code:	LKF
Regulation Number:	unknown (Class II)
Predicate Device(s):	VCARE Rectractor/Elevator K955446

MAR 12 2010

Device Description

VCARE Dx™ uterine manipulator/injector cannula is a sterile, disposable, single-patient use device which consists of a hollow, rigid, insulated, anatomically curved manipulator tube (OD: 5mm; length: 48cm (19") including handle) with an inflatable PVC intrauterine balloon at the proximal end, graduations (cm) along the shaft measuring distance from the proximal end and a molded handle at the distal end for maintaining proper attitude of the uterus. The graduations on the shaft of the VCARE Dx™ can be used as a guide for comparison to a graduated uterine sound, if one is used. The intrauterine balloon is inflated by passing air via a standard syringe (not included) through the distally located pilot balloon/valve assembly. The internal tip of the manipulator tube is open to allow direct intrauterine introduction of dye/contrast media via the injector port on the rear of the handle, when prescribed. VCARE Dx™ incorporates a component that seats against the cervix providing a positive stop from over-penetration of the uterine cavity and counter traction with the intrauterine balloon for effective manipulation. The rear portion of the device is secured at its proper depth with a locking mechanism situated at the rear of the main tube and external to the patient.

Indications for Use

VCARE Dx uterine manipulator/injector cannula is indicated for manipulation of the uterus, and injection of fluids during laparoscopic gynecologic procedures such as laparoscopic supracervical hysterectomy, minilap tubal ligation, laparoscopic tubal occlusion or diagnostic laparoscopy.

Risk Mitigation Table

Below is a summary of risks common to uterine manipulators and how this submission addresses those risks.

Identified Risk	**Mitigation Measures**
Inadequate Device Performance	Performance Testing (Section 8)
Adverse Material Reactivity	Biocompatibility Information (Section 9)
Contamination	Sterilization and Packaging (Section 10)
Improper Use	Labeling (Section 7)

An in-depth risk management analysis, including mitigation measures, was performed on VCARE Dx. The results are provided under Section 5.

Performance Verification

A comparison test was performed between VCARE Dx (subject device) and VCARE (predicate device) to test similar performance specifications.

The documented evidence showed that VCARE Dx is substantially equivalent to VCARE due to a significant number of identical parts. All results are favorable in establishing substantial equivalence between the design of VCARE Dx and the predicate device VCARE.

The design of VCARE Dx is substantially equivalent to VCARE with regards to function and specifications.

Conclusion

Supporting information per this premarket submission confirms that the ConMed VCARE Dx uterine manipulator/injector cannula is substantially equivalent to its predicate device, VCARE K955446.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Sarah Rizk
Regulatory Affairs Specialist
ConMed Corporation
525 French Road
UTICA NY 13502

MAR 12 2010

Re: K093556
Trade/Device Name: VCARE Dx Uterine Manipulator/Injector Cannula
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: LKF
Dated: February 24, 2010
Received: February 26, 2010

Dear Ms. Rizk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K093556

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Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093556